A Prospective Randomized Blinded Controlled Trial Comparing Clinical Outcomes in Cardiac Surgical Patients Who Receive Sugammadex vs. Placebo

Study Protocol

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1.0 Study Title: A Prospective Randomized Blinded Controlled Trial Comparing Clinical Outcomes in Cardiac Surgical Patients Who Receive Sugammadex vs. Placebo

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2.1 Objectives & Hypothesis

Primary Objective

To compare the difference in the number of elective or urgent cardiac surgical patients undergoing cardiopulmonary bypass at Endeavor Health in the sugammadex vs. placebo groups who meet the Society of Thoracic Surgery (STS) quality benchmark of early extubation criteria (within 6 hours of end of surgery).

Hypothesis:

Administering sugammadex 15 minutes after arrival to the ICU after elective or urgent cardiac surgery will result in a statistically significant increase in the number of patients who meet the STS quality benchmark of extubation within 6 hours of the end of surgery when compared to patients who do not receive neuromuscular blockade (NMB) reversal.

Primary Endpoint

1. A comparison in the difference in the number of patients who receive sugammadex and meet the STS 6-hour extubation criteria from the end of surgery vs. those that do not receive neuromuscular blockade reversal.

Secondary Objectives

All secondary outcomes will be exploratory only.

1. To compare time to first extubation in each group
2. To compare time from administration of sugammadex vs. placebo to achieve a TOF ratio >0.9 prior to extubation
3. To compare ICU length of stay (hours) in each group
4. To compare hospital length of stay (days) in each group
5. To compare the incidence of reintubation post-extubation in each group
6. To compare the incidence of post-extubation pneumonia as diagnosed using the STS definition of pneumonia which states that there should be a physician diagnosis documented in the medical record based on radiologic evidence as well as symptoms, (i.e., fever, leukocytosis, sputum, etc.)
7. To compare the number and duration of hypoxemic episodes within 24 hours of extubation based on the Berlin definition of hypoxemia [1]
    a. Mild Hypoxemia (PaO2/FiO2 ≤ 300 and >200 mmHg)
    b. Moderate Hypoxemia (PaO2/FiO2 ≤ 200 and >100 mmHg)
    c. Severe Hypoxemia (PaO2/FiO2 ≤100 mmHg).
8. To compare the number and duration of non-invasive ventilation (i.e. BiPAP, HFNC, etc.) over the first 24 hours post-extubation in each group
9. To compare cost of ICU stay (collected from hospital billing data)
10. To compare nursing perception of cardiac surgical patients' ICU quality of recovery within first 24 hours of ICU length of stay (using a 5-point Likert Scale, 5=very satisfied, 4=somewhat satisfied, 3=neutral, 2=somewhat dissatisfied, 1=very dissatisfied) in the sugammadex vs. placebo groups.

Hypothesis:

Administering sugammadex 15 minutes after arrival to the ICU after elective or urgent cardiac surgery will result in a clinically and statistically significant decrease in time to first extubation, hospital and intensive care unit length of stay, cost of the ICU stay, the incidence of reintubation and post-

extubation pneumonia, the number and duration of mild-moderate and severe hypoxemic episodes within the first 24 hours of extubation, decrease the number of patients who require non-invasive ventilation post-extubation and the duration of use of non- invasive ventilation during the first 24 hours post-extubation, and will improve nursing perception as it relates to cardiac surgical patients' ICU quality of recovery within the first 24 hours when compared to those patients who do not receive sugammadex.

2.2 Background and Rationale, Significance of Selected Topic & Preliminary Data

Extended durations of mechanical ventilation in cardiac surgical patients may increase the risk of respiratory complications, intensive care unit (ICU) and hospital length of stay, and immobility. Reducing the length of postoperative mechanical ventilation in this patient population can lead to improved outcomes.[2,3,4] Therefore, the Society of Thoracic Surgery (STS) developed a fast track extubation benchmark metric to be within 6 hours of the end of surgery.[5]

The use of NMB without routine NMB reversal in cardiac surgical patients may serve as an obstacle to achieving the STS extubation benchmark goal, while also increasing the risk of complications. Without routine NMB reversal, cardiac surgical patients are typically transferred to the ICU with the endotracheal tube remaining in the airway. The NMB blockade is typically metabolized by the liver/kidney and then patients are liberated from the ventilator in the ICU afterwards. The proposed reason for this strategy is to reduce the potential risk of rebleeding or arrhythmias due to a sympathetic response from patients. A survey among 495 cardiac anesthesiologists in the U.S. in 2002 suggested that only 9% of anesthesiologists routinely reverse NMB in these patients prior to extubation.[6]

The lack of reversal drug use among any surgical patient population could result in residual NMB, which is defined by a train of four ratio < 0.9.[7] Patients who do not meet this level of neuromuscular recovery are at risk for adverse outcomes including hypoxemia, airway obstruction, impaired swallowing function, increased risk for aspiration, prolonged length of stay, postoperative respiratory complications, and need for reintubation.[8,9]

Sugammadex is a novel cyclodextrin, and its lower adverse respiratory and cardiovascular effects, compared to neostigmine combined with a cholinesterase receptor inhibitor,[10] suggest it may be a safe and effective NMB reversal agent for cardiac surgical patients. A very recent study on non-surgical patients concluded that there is a need for randomized controlled trials which would evaluate the effects of sugammadex [11]. Unfortunately, the data regarding residual NMB and, especially, sugammadex, in cardiac surgical patients is limited. A prospective observational cohort of 50 cardiac surgical patients, suggested that 66% of patients had significant residual neuromuscular blockade within 1 hour postoperatively.[9] This study also reported the possibility of post-traumatic stress disorder related to patients regaining some level of consciousness during residual paralysis in the post-operative period. A recent multicenter international study among 42 hospital centers suggested that the use of NMB is a risk factor for postoperative pulmonary complications.[12] The authors surmise that the cause of pulmonary complications in cardiac surgical patients stemming from the use of NMB may either come from the lack of routine neuromuscular monitoring or the presence of residual NMB in the postoperative period.[12]

Recent literature has indicated potential advantages associated with NMB reversal in cardiac surgery patients. A prospective randomized study of 60 pediatric cardiac surgery patients suggested that the administration of sugammadex compared to neostigmine resulted in decreased time to extubation and a reduction in hospital length of stay.[13] However, this was a small study and lacked a placebo group in children. A retrospective study published as a correspondence by Lan et al. suggested that sugammadex resulted in a statistically significant reduction in mechanical ventilation time, ICU, and hospital length of stay. This study was a very small study and did not match the patients in each group for important variables that may affect the endpoints such as

liver/kidney disease, cardiopulmonary bypass time and intraoperative amounts of sedative and narcotics.[14] Another study sponsored by Merck by Bardia et al. (provided by Merck), randomized 90 elective cardiac surgical patients undergoing cardiopulmonary bypass to receive either sugammadex or placebo 30 minutes after arrival to ICU. The sugammadex group had a statistically significant reduction in time to extubation, but no other differences were detected. However, this study enrolled elective healthier cardiac surgical patients (with ejection fraction >45%) and did not use neuromuscular monitoring to confirm the important TOF >0.9 prior to extubation. Therefore, outcome data in sicker elective or urgent cardiac surgical patients who are appropriately monitored for residual NMB in the postoperative period prior to extubation and who receive sugammadex have not been acquired. In addition, no present studies have investigated whether sugammadex can increase the percentage of cardiac surgical patients who meet the STS fast track extubation criteria by reducing the risk of residual NMB and subsequently decreasing the time to extubation. This remains a national benchmark that many hospitals use for quality reporting.

Our clinical practice at Endeavor Health for cardiac surgical patients has changed as it relates to managing NMB. Prior to 2019, the clinical care team (cardiac surgery, intensive care, nursing, and anesthesia) did not routinely discuss dosing of NMB during the handoff of patients to the ICU. Anesthesia professionals also did not routinely reverse NMB in post-cardiac surgical patients. In the latter half of 2019, our care team developed a multidisciplinary handoff checklist (with several key components of the patient's medical history and the course of the surgery), which includes discussion regarding the last dose of NMB. We believe that the addition of the standardized handoff checklist helped our team to meet the STS early extubation national benchmark. As a quality improvement project, our team retrospectively compared patients who received sugammadex vs. those that did not during 2018-2021 and found a 15% absolute difference (96.7% vs. 81.3%, p=0.0428) in patients who met STS early extubation criteria and over a 1-hour reduction in time to extubation (3.6±2.0 vs. 4.7±2.9, p=0.0098) in the sugammadex group when both groups were appropriately matched for significant confounding variables (Table 1). Currently, it is no the standard of care to reverse all cardiac surgical patients after their surgeries.

Table 1. Propensity Score Matching (1:5) Between Reversal and No Reversal Groups (matched groups for kidney/liver disease, cardiopulmonary bypass time, surgery type, and intraoperative amounts of sedatives and narcotics).

	Total (N=180)		No Reversal (N=150)		Reversal (N=30)		p-value
Variables	n	% or mean ± SD	n	% or mean ± SD	n	% or mean ± SD	
Outcome measures							
First Extubation Time (hrs)	180	4.5±2.8	150	4.7±2.9	30	3.6±2.0	0.0098*
≤6	151	83.9	122	81.3	29	96.7	0.0428*
>6	29	16.1	28	18.7	1	3.3	

2.3 Study Design

Based on our retrospective analysis of our quality data, we propose a prospective randomized blinded controlled trial to compare the difference in the number of elective or urgent cardiac surgical patients undergoing cardiopulmonary bypass at Endeavor Health in the sugammadex vs. placebo groups who meet STS early extubation criteria. We will stratify patients based on whether they received elective or urgent cardiac surgery under cardiopulmonary bypass. We will investigate the following outcomes as we believe that complete reversal of NMB with sugammadex may directly improve the following endpoints by eliminating the unwanted effects of residual NMB: difference in number of patients in each group who meet STS extubation fast track criteria, time to first extubation, time from administration of sugammadex vs. placebo to achieve a TOF ratio ≥ 0.9 prior to extubation, ICU length of stay, hospital length of stay, incidence of reintubation post-extubation, incidence of post-extubation pneumonia, cost of ICU stay, nursing perception of cardiac surgical

patients ICU quality of recovery within first 24 hours (using a 5 point Likert Scale, 5=very satisfied, 4=somewhat satisfied, 3=neutral, 2=somewhat dissatisfied, 1=very dissatisfied).

The following secondary outcomes will be obtained retrospectively from the patient's EMR (without need for patient contact) as we believe that complete reversal of NMB with sugammadex may directly improve the following endpoints: the number and duration of mild, moderate, and severe hypoxemic episodes within 24 hours of extubation. Hypoxemic episodes will be identified by using the Berlin definition of hypoxemia [1] and the blood gases that were collected on these patients within the first 24 hours; the number and duration of non-invasive ventilation (i.e. BiPAP, HFNC, etc.) within the first 24 hours post-extubation will be compared between groups.

We plan to enroll 152 study subjects undergoing cardiopulmonary bypass at Endeavor Health. Subjects will be randomized by simple randomization technique using computer generated random numbers to assign subjects to either the sugammadex or placebo group (approximately 76 subjects per treatment group). Subjects will be recruited from the Cardiac Surgical Clinic with the help of our cardiac surgical team and our research coordinator. To be eligible to participate in this study, a subject must meet the following inclusion criteria:

Inclusion Criteria:

1. Subject must be an elective or urgent cardiac surgical patient undergoing cardiopulmonary bypass at Endeavor Health.
2. Male or female subject aged 21 to 90 years, at the time of consent.
3. Subjects who are eligible for fast track extubation as defined by those patients who **plan on being extubated within 24 hours of the end of surgery and optimally within the 6-hour STS benchmark time from end of surgery.**

Exclusion Criteria:

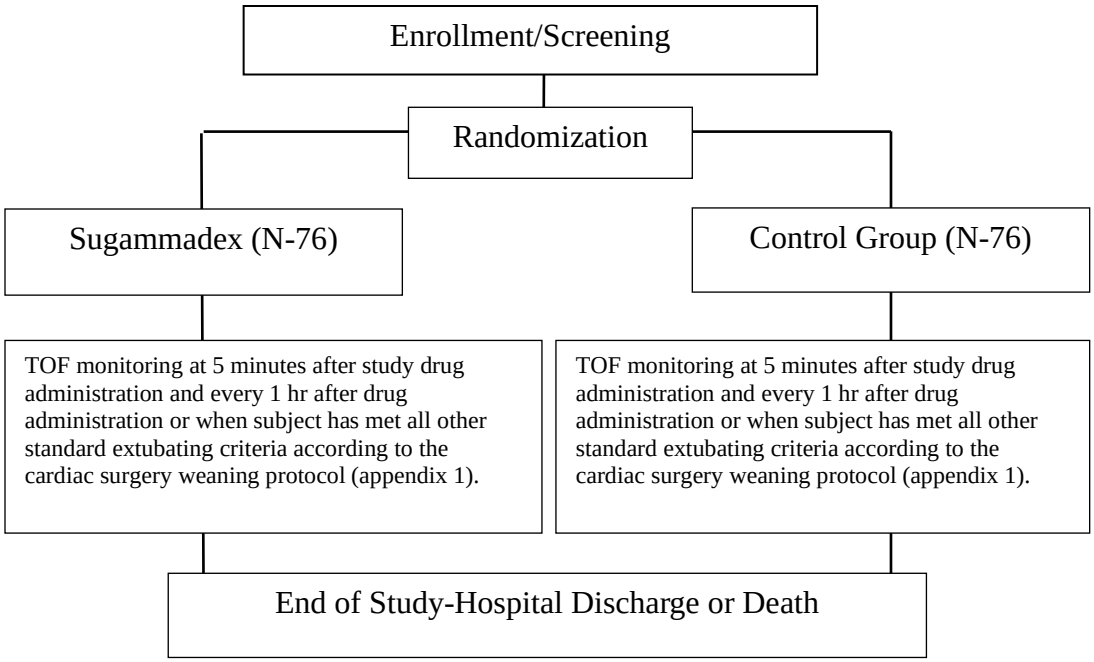
1. Subjects having emergency cardiac surgery.
2. Subjects who are not eligible to be extubated within 24 hours of the end of surgery.
3. Subjects with neuromuscular disorders.
4. Subjects on home oxygen.
5. Subjects who have known allergies or reactions to rocuronium or sugammadex.
6. Subjects with anticipated need for prolonged intubation by the clinical treating team.
7. Subjects with a history of opioid abuse.
8. Subjects on mechanical circulatory support.
9. Subjects who have end stage renal disease requiring dialysis

Subjects who meet all the inclusion criteria and none of the exclusion criteria may be included in the study.

2.4 Diversity & Inclusion

We anticipate enrolling approximately 152 adult subjects' ages 21 to 90 years. There are no exclusions based on gender or sex and we expect the enrollment of men and women to be equal.

2.5 Study Flowchart



2.6 Study Procedures

Study subjects will be recruited from the Cardiac Surgical Clinic at Endeavor Health. The research team will screen all potential subjects seen at the Cardiac Surgical Clinic. Eligible subjects may be contacted in person and/or by phone to discuss the study. Informed consent can be obtained in-person in the surgeon's clinic prior to the subjects' surgery date or via an e-consent link directly from REDCap. Preferred email addresses will be confirmed prior to sending the study consent form. The study staff will document in EPIC a telephone call that will occur with patients prior to their surgery. Documentation of this call will include that the patient confirms receipt of the consent. All enrolled subjects will be enrolled only once and will be assigned a subject identification number during the consent visit that will be used on all subject documentation. The cardiac surgeon will identify those patients who he believes will meet the criteria for fast extubation within 24 hours. Those patients who have neuromuscular disorders, on home oxygen, on mechanical circulatory support or require mechanical circulatory support postoperatively, who are on > 2 vasopressors or inotropes postoperatively, have an intraoperative estimated blood loss of > 1liter excluding cell saver, difficult airway identified by anesthesia team in the operating room, or chest tube output >400cc/hr. in first hour of postoperative period will be excluded from the study after potential enrolment. All other patients will be enrolled in the fast-track limb and are anticipated to be extubated within 24 hours.

All subjects enrolled in the study will receive the standard general anesthetic with inhaled sevoflurane to keep the bispectral index (BIS®) between 40-60. Fentanyl or sufentanil will be used for analgesia and will be up to the provider on when to administer. Induction drugs for general anesthesia will be up to the anesthesia providers. Subjects will be given rocuronium exclusively for neuromuscular blockade for intubation and maintenance of neuromuscular blockade during the operation. Upon surgical closure, the anesthesia team will measure a twitch count with the neuromuscular monitor and target that count between 2/4-4/4 at that time. Intraoperative providers will document the TOF count prior to transporting the subject to the ICU. Postoperatively, all subjects will be transferred to the ICU on propofol infusions or midazolam boluses, and dosing will be left up to the providers. After arrival to the ICU, patients will be randomized via a separate randomization list created by a random sequence generator. The investigator and research coordinator will then provide the anesthesia professional who is administering either placebo or sugammadex with the drug.

After the ICU signout has been completed (15 minutes after subject arrives to ICU), subjects will be administered either sugammadex (2mg/kg assuming a twitch count of 2-4/4) or placebo by the anesthesia

provider. If the twitch count is less than 2, the subjects in the sugammadex group will be given 4mg/kg. Five minutes after administration of the study drug, a quantitative neuromuscular monitor (Tetragraph, Senzime, Uppsala, Sweden) will be used to record the TOF ratio and compare it to baseline value. The surgical and ICU teams will be blinded to the administration of the study drug. The subjects will also be blinded to the administration of the study drug.

Subjects will be extubated when the following criteria have been met: (see Appendix 1). In addition to the weaning protocol, all subjects must meet the TOF ≥0.9 prior to extubation. The TOF monitoring will occur 5 minutes after administration of the study drug and every hour after that or when the subject has met all other standard extubation criteria according to the cardiac surgery weaning protocol.

2.7 Study Duration

Study duration will take approximately 2 years including enrollment, data collection, data analysis and study close out. **Enrolment is expected to be completed in 1 year.**

2.8 Statistical Analysis and Sample Size Justification

Data analysis will be performed by Chi Wang, PhD. Comparison data will be analysed between groups using Student t-test for continuous variables and Chi-square test for categorical variables. For continuous endpoints, normality should be checked for a student t-test, if not normally distributed an alternative statistical method will be used**.** We anticipate that patient demographic and clinical characteristics will be similar between the two experimental groups due to random assignment. However, if we observe any differences in patient demographics and preoperative or intraoperative measures between the two groups, we will control these variables in the multivariable analysis.

Power/Sample Size

We conducted the power analysis based on our preliminary data cited above. A total of 152 patients (76 in each group) will achieve an 80% power to detect a 15%-point difference (95% vs. 80%) in proportion of patients who meet STS early extubation criteria (within 6 hours of end of surgery) between intervention and placebo groups using a two-sided alpha of 0.05. This sample size will also allow us to detect a medium effect size of d=0.46 in time to extubation between the two groups with an 80% power. All secondary outcomes will be exploratory only.

2.9 Specific Drug Supply Requirements

Merck will provide the study drug (sugammadex) to the Endeavor Health Pharmacy team as this is not current standard of care to administer sugammadex to this patient population. The pharmacy will prepare a 5cc syringe (labelled study drug) to the anesthesia professional who will administer the study drug in the ICU or the placebo (which will be saline in the same 5cc syringe). Our pharmacy will be responsible for acquiring the saline placebo for the study. Our pharmacy will also be responsible for filling individual patient containers, labeling the containers and performing the blinding of the supplies.

The investigators will be responsible for the destruction of the supplies at the study center pursuant to the ICH/GCP Guidelines, local regulations, and the investigator's institutional policies. Clinical supplies are dispensed in accordance with the protocol. The investigators will be responsible for keeping accurate records of the clinical supplies, the amount dispensed to the patients, and the disposition at the end of the study.

2.10 Adverse Experience Reporting

The PI and Co-PI will review the progress of the project and data being collected to ensure that potential adverse events are identified and responded to appropriately. We will report any adverse events to the IRB with the required documentation for reporting adverse events and serious events.

Participants will have phone numbers to call the research team if they have any problems.

2.11 Unblinding
In the event that a patient becomes ineligible to continue in the study during or after surgery, the patient will be notified in person by the research staff immediately upon when the patient is conscious to understand why they are no longer in the study. The patients will continue to receive the standard of care throughout their hospital stay at Endeavor Health. Some of the reasons why patients may not continue in the study is requirement for circulatory support that was unanticipated and required after the operation, any reason why a patient might require prolonged intubation (> 24hours) such as excessive bleeding (>2L estimated blood loss), requirement for more than two vasopressors or inotropes or concern for reoperation requirement and significant hypoxemia due to fluid overload.

2.12 Itemized Study Budget (see attachment 1 for budget excel spreadsheet)

2.13 Role of Key Personnel:

Roles and responsibilities of personnel are delegated per the delegation log.

Study duration will take 2 years including enrollment, data collection, data analysis and study close out. Enrollment is expected to be completed in 1 year.

2.14 References:

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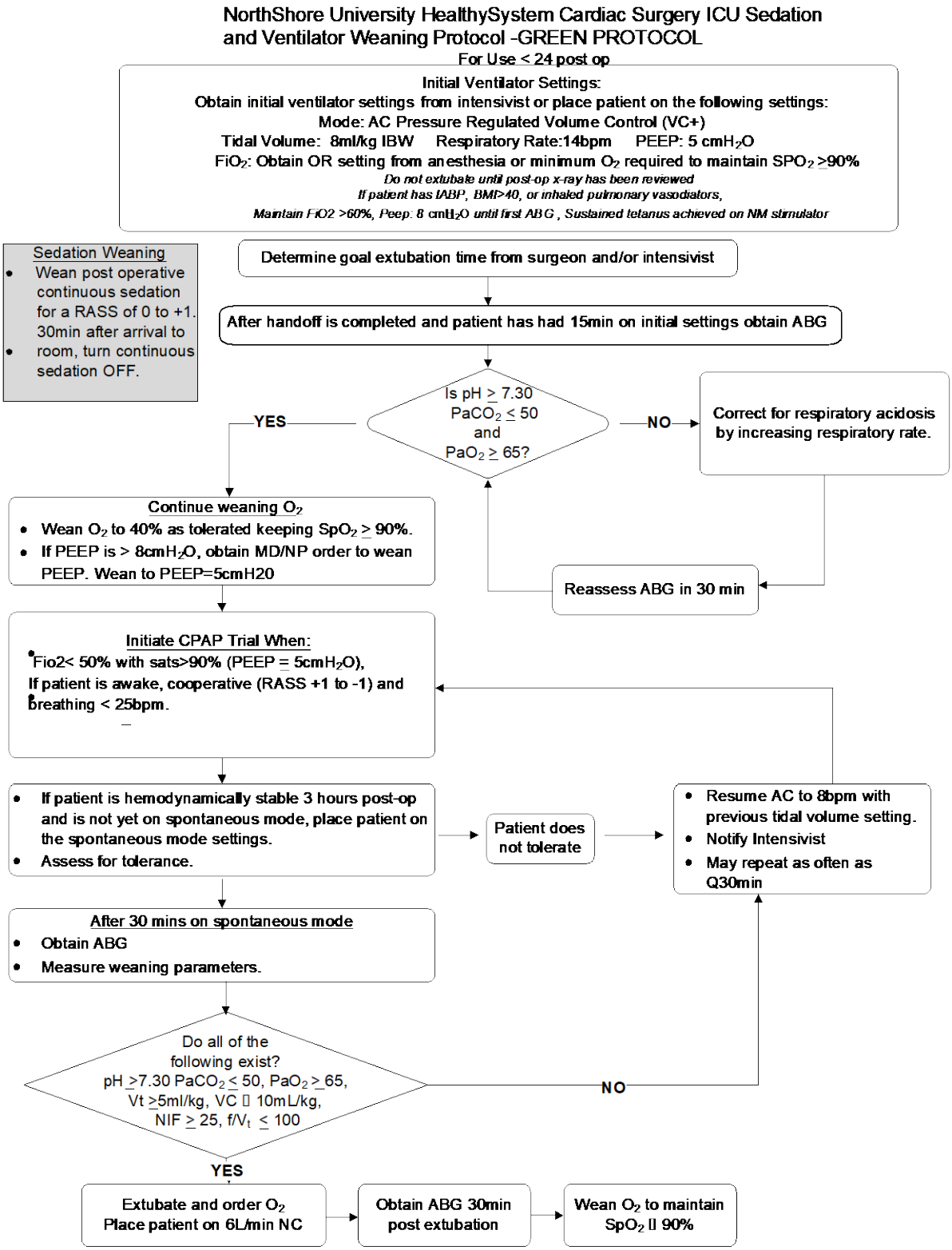
2.15 Publication Plan

We plan to complete data analysis in May of 2024 and start manuscript preparation in June of 2024. We anticipate submitting one manuscript to Anesthesiology at the end of June of 2024. We hope to present this data at national meetings including: the Annual ASA 2024, the Annual SCA meeting 2024, and the 2024 Society of Critical Care Medicine Congress.

Timeline: May 2023-May 2024

1. April 2023: Receive IRB approval to proceed with study
2. May 2023-Begin enrolling participants for study
3. May 2024-Stop enrolling patients
4. May 2024-Data Analysis
5. June 2024-Manuscript Preparation.


NorthShore University HealthySystem Cardiac Surgery ICU Sedation and Ventilator Weaning Protocol -GREEN PROTOCOL
For Use < 24 post op
Initial Ventilator Settings:
Obtain initial ventilator settings from intensivist or place patient on the following settings:
Mode: AC Pressure Regulated Volume Control (VC+)
Tidal Volume: 8ml/kg IBW Respiratory Rate:14bpm PEEP: 5 cmH2O
FiO2: Obtain OR setting from anesthesia or minimum O2 required to maintain SPO2 ≥90%
Do not extubate until post-op x-ray has been reviewed
If patient has IABP, BMI>40, or inhaled pulmonary vasodiators,
Maintain FiO2 >60%, Peep: 8 cmH2O until first ABG , Sustained tetanus achieved on NM stimulator
Sedation Weaning
Wean post operative continuous sedation for a RASS of 0 to +1. 30min after arrival to room, turn continuous sedation OFF.
Determine goal extubation time from surgeon and/or intensivist
After handoff is completed and patient has had 15min on initial settings obtain ABG
Is pH ≥ 7.30 PaCO2 ≤ 50 and PaO2 ≥ 65?
YES
NO
Correct for respiratory acidosis by increasing respiratory rate.
Continue weaning O2
Wean O2 to 40% as tolerated keeping SpO2 ≥ 90%.
If PEEP is > 8cmH2O, obtain MD/NP order to wean PEEP. Wean to PEEP=5cmH20
Reassess ABG in 30 min
Initiate CPAP Trial When:
Fio2< 50% with sats>90% (PEEP = 5cmH2O),
If patient is awake, cooperative (RASS +1 to -1) and breathing < 25bpm.
If patient is hemodynamically stable 3 hours post-op and is not yet on spontaneous mode, place patient on the spontaneous mode settings.
Assess for tolerance.
Patient does not tolerate
Resume AC to 8bpm with previous tidal volume setting.
Notify Intensivist
May repeat as often as Q30min
After 30 mins on spontaneous mode
Obtain ABG
Measure weaning parameters.
Do all of the following exist?
pH ≥7.30 PaCO2 ≤ 50, PaO2 ≥ 65,
Vt ≥5ml/kg, VC 10mL/kg,
NIF ≥ 25, f/Vt ≤ 100
NO
YES
Extubate and order O2
Place patient on 6L/min NC
Obtain ABG 30min post extubation
Wean O2 to maintain SpO2 II 90%